K112607

JUN - 7 2012

6. 510(k) Summary

Manufacturer:	SpineVision, S.A. Antony Parc II 10 Place du General de Gaulle CS 70001 Antony Cedex 92184, France
Date:	May 28, 2010
Submitted by:	SpineVision, S.A.
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US Agent Information	Orgenix LLC Mr. Donald W. Guthner 111 Hill Road Douglassville, PA 19518 +1-646-460-2984 +1-484-363-5879 (FAX)
Classification Name:	Pedicle Screw Spinal System
Common/Usual Name:	Rod and Screw Spinal Instrumentation
Proprietary Name:	SpineVision LUMIS™ Cannulated Polyaxial Pedicle Screw Fixation System SpineVision U.L.I.S.™ Polyaxial Pedicle Screw Fixation System
Performance standards:	The *SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System)* instrumentations were mechanically tested to the following standards – ASTM F1717, ASTM F543, ASTM F2193 and ASTM F 1798 (current versions).
Classification no.:	21 CFR 888.3070 NKB, MNI, MNH, KWQ, KWP – Pedicle Screw Spinal System Class III
Substantial Equivalence:	Substantial equivalence for the *SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System)* instrumentations is

based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions:

- K033508 SpineVision PLUS System with Multi-axial Screws
- K111479 Globus Medical Revere® Crosstop™ Spinal Stabilization System.

Predicate Devices: The subject device is substantially equivalent to similar previously cleared devices.

Device Description: The *SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System)* instrumentations are composed of cannulated (LUMIS™) and non-cannulated (U.L.I.S.™) pedicle screws and fixation rods (SpineVision Unithread ™ rods). Their components can be rigidly assembled in a variety of constructs, each corresponding to the needs and anatomy of a specific patient.
These constructs are assembled using specific instruments.
The components of the U.L.I.S.™ and LUMIS™ systems are made from ASTM F136 titanium alloy (Ti-6Al-4V ELI) complying with ASTM F136 (ISO 5832-3

Intended Use: When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for:

- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- spinal stenosis
- tumors
- failed previous fusion (pseudoarthrosis)

The U.L.I.S.™ and LUMIS™ systems are pedicle screw systems indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
- receive fusions using autogenous bone graft only;
- have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and
- have the device removed after the development of a solid fusion.

In addition, the U.L.I.S.™ and LUMIS™ systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and

chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T10-S1):

- degenerative spondylolisthesis with objective evidence of neurologic impairment
- fracture
- spinal tumor
- failed previous fusion (pseudoarthrosis)

Summary of Technological Characteristics	The *SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System)* instrumentations are manufactured in Titanium alloy complying with ASTM 136. The LUMIS™ Pedicle screw system is cannulated. The devices provide correction and rigid stabilization of the spine during development of solid bone fusion following corrective spine surgery for a number of indications (listed above).
Non-Clinical Testing	The *SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System)* instrumentations were tested (worse case) according to the following standards: ASTM F1717 - Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model ASTM F543 - Standard Specification and Test Methods for Metallic Medical Bone Screws ASTM F2193 - Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System ASTM F1798 - Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants Test results indicated substantial performance of the worse case in side-by-side testing with the predicate device. Sterilization validation according to the following standards: - ANSI/AAMI/ISO 17665-1:2006 - ANSI/AAMI ST79:2010, A1:2010 and A2:2011
Supporting Documentation	Published retrospective clinical data for devices similar to the *SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System)* devices were provided in support of this application. This clinical data demonstrated pedicle screws posed no new risks to pediatric patients.
Conclusion	The information discussed above demonstrates that the *SpineVision Universal Lumbar Intuitive System (U.L.I.S.™*

System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) devices are effective and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 7 2012

SpineVision, S.A.
c/o Orgenix LLC
Mr. Donald W. Guthner
Consultant
111 Hill Road
Douglassville, Pennsylvania 19518

Re: K112607
Trade/Device Name: Spinevision LUMIS Cannulated Polyaxial Pedicle Screw Fixation System and ULIS Polyaxial Pedicle Screw Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: May 28, 2012
Received: May 30, 2012

Dear Mr. Guthner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112607

5. Indications for Use

510(k) Number (if known): **K112607**

Device Name: **SpineVision LUMIS™ Cannulated Polyaxial Pedicle Screw Fixation System**
SpineVision U.L.I.S.™ Polyaxial Pedicle Screw Fixation System

When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for:

- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- spinal stenosis
- tumors
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- fracture
- spinal tumor
- failed previous fusion (pseudoarthrosis)

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112607